

REMARKS

Entry of the foregoing, further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Status

As is correctly reflected in the Office Action Summary, Claims 2, 3, 8-17 and 22-31 are pending. Claims 1, 4-7 and 18-21 have been cancelled. Claims 2, 3, 8-17 and 22-31 stand rejected.

Summary of Claim Amendments

By the foregoing amendments, independent Claims 2 and 22 have been amended to specify that "said disorders of the barrier function of human skin are selected from the group consisting of disorders of the secretion of epidermal lipids, skin disorders in premature babies born before 33 weeks gestation, chapped lips, and blisters resulting from mechanical friction." Support for these amendments may be found throughout the Specification, and at least at Paragraph [0024] of the Specification. Accordingly, no new matter has been added.

Objection to Specification

The Specification has been objected to as referencing an unclear copending application. *See Official Action, Page 3.* By the foregoing amendments, Applicants have amended Paragraph [0002] of the Specification to include the now-available serial number for sister U.S. Patent Application Serial No. 09/933,835, Attorney Docket No. 016800-452. Accordingly, Applicants believe the foregoing objection has now been rendered moot.

Rejections Under 35 U.S.C. § 112, First Paragraph – Scope of Enablement

Claims 2, 3, 8-17, and 22-31 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly lacking sufficient enablement. *See Official Action, Pages 2-6.* This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejections, but solely to facilitate prosecution, Applicants have amended independent Claims 2 and 22 to specify that "said disorders of the barrier function of human skin are selected from the group consisting of disorders of the secretion of epidermal lipids, skin disorders in premature babies born before 33 weeks gestation, chapped lips, and blisters resulting from mechanical friction." Because the Examiner admits that the Specification is enabling for such particular skin disorders, Applicants believe these amendments have rendered moot the outstanding scope of enablement rejections, and respectfully request withdrawal thereof. *See Official Action, bottom of Page 3.*

Claims 17 and 31 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly lacking sufficient enablement. *See Official Action, Pages 6-11*. This rejection is respectfully traversed.

"The test of enablement is not whether **any** experimentation is necessary, but whether, if experimentation is necessary, it is **undue**." *See M.P.E.P. § 2164.01* (emphasis added). Applicants respectfully maintain that, especially in light of the present amendments, one of skill in the art can readily both make and use Applicants' invention described in Claims 17 and 31. The meaning, use, and preparation of retinoids, vitamin D, corticosteroids, agents for combating free radicals, α -hydroxy acid, α -keto acid, and ion channel blockers are art-appreciated and require no experimentation, let alone no *undue* experimentation to arrive at. Accordingly, Applicants respectfully request withdrawal of the scope of enablement rejections of Claims 17 and 31.

Rejections Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness

Claims 2, 3, 8-17, and 22-31 were rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite. *See Official Action, Pages 11-12*. According to the Examiner, "disorders of the barrier function of human skin" is indefinite. These rejections are respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended independent Claims 2 and 22 to specify that "said disorders of the barrier function of human skin are selected from the group consisting of disorders of the secretion of epidermal lipids, skin disorders in premature babies born before 33 weeks gestation, chapped lips, and blisters

resulting from mechanical friction.” Applicants believe these amendments have rendered moot the foregoing indefiniteness rejections, and respectfully request withdrawal thereof.

Rejections Under 35 U.S.C. § 103(a) Over Bernardon

Claims 2, 3, 8-17, and 22-31 were rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over U.S. Patent No. 5,763,487 to Bernardon *et al.* (“Bernardon”). See *Official Action, Pages 12-15*. These rejections are respectfully traversed.

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. See *M.P.E.P. § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. See *M.P.E.P. § 2142*.

Moreover, mere identification of each claimed element in the prior art is NOT sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there “must be a teaching or suggestion within the prior art, or within

the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357. Applicants maintain that a *prima facie* case of obviousness cannot be made out using Bernardon because Bernardon fails to disclose all elements of Applicants' amended claims. Applicants further maintain that a *prima facie* case of obviousness cannot be made out because there is nothing in Bernardon to motivate or suggest to one of skill in the art to modify Bernardon's methods so as to treat the now-enumerated disorders of the barrier function of skin. By extension, even if one of skill in the art had been so motivated, there would be no reasonable expectation of success for such a modification, and thus no *prima facie* case of obviousness, because the disorders addressed by Bernardon are so very different than disorders of the barrier function of skin.

In view of the foregoing, Applicants maintain that Bernardon fails to render amended Claims 2, 3, 8-17, and 22-31 obvious.

Judicially-Created Double-Patenting Rejections

The pending claims have been rejected under the judicially-created doctrine of double-patenting. *See Official Action, Pages 15-18*. Specifically, the pending claims have been rejected as obvious over Claims 16 and 17 of U.S. Patent No. 5,763,487; Claims 23, 26, 28, and 35-36 of U.S. Patent No. 6,156,750; and Claims 32-41 of U.S. Patent Application Serial No. 10/224,449. These rejections are

respectfully traversed. However, Applicants will revisit the option of providing one or more terminal disclaimers regarding the foregoing patents and patent application, should instant Claims 2, 3, 8-17, and 22-31 be found otherwise allowable.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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Date: January 3, 2005

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